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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/566,927

09/13/2006

Stephen Martone

386/05062

1141

44909

7590

02/24/2010

PRTSI

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EXAMINER

NGUYEN, TINA MY PHUONG

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

02/24/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/566,927	Applicant(s) MARTONE ET AL.	
	Examiner TINA NGUYEN	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/16/2009 (election).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 43-50 and 73-91 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 43-50 and 73-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 February 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>09/10/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group V (claims 43-50) in the reply filed on 11/16/2009 is acknowledged. The cancellation of claims 1-42 and 51-72 and new claims 73-91 are acknowledged. Applicant's Remarks dated 11/16/2009 state that the application contains claims 43-50 and 73-84 upon entry of the amendment, however, the Examiner considers this to be a typo and states that claims 43-50 and 73-91 are currently pending in the application. However, if this is incorrect, correction is requested.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the connection of the external and internal sheath to the proximal connector (in claim 79) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering

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of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

3. Claim 83 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 83 reads that the distal ends of the internal and external sheaths are foldable. However, applicant's Specification only mentions the external sheath being foldable (page 10, lines 19-26).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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5. Claims **43-45, 47, 49, 73-77, 79, 82-84, and 91** are rejected under 35 U.S.C. 102(b) as being anticipated by Nakao et al. (U.S. Patent 5,217,001).

6. As to claim **43**, Nakao discloses a sheath (Figs. 7-10) assembly for a probe, comprising: an internal sheath (80) configured to isolate a probe from body fluids; and an external sheath (94) surrounding the internal sheath, the internal and external sheaths being connected to each other wherein at least the distal ends of the internal and external sheaths are flexible (because flexible is a relative term, everything has a certain amount of flexibility in it).

7. As to claim **44**, Nakao discloses that the internal and external sheaths are connected to each other over at least one axial line (Col. 8, lines 39-44) extending over a segment of the length of the sheaths.

8. As to claim **45**, Nakao discloses that the internal and external sheaths are connected over at least two longitudinal lines (see Figs. 7 & 9).

9. As to claim **47**, Nakao discloses that the internal and external sheaths are connected radially symmetrically (Fig. 9).

10. As to claim **49**, Nakao discloses that the internal and external sheaths coextend at their distal ends, such that their distal ends extend to a same point (Fig. 8).

11. As to claim **73**, Nakao discloses that there is at least one channel is defined between the external sheath and the internal sheath along at least a portion of the sheath assembly (Fig. 10).

12. As to claim **74**, Nakao discloses that the at least one channel is open at the distal end of the sheaths (Col. 8, lines 39-43).

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13. As to claim **75**, Nakao discloses that the channel does not surround the entire internal sheath (Fig. 10).

14. As to claim **76**, Nakao discloses that there are two channels (channels with 97 and 99, Fig. 10).

15. As to claim **77**, Nakao discloses that the over most of the length of the sheath assembly, the external sheath is attached to the internal sheath along at least one longitudinal line (Figs. 7 & 10, Col. 8, lines 39-43).

16. As to claim **79**, Nakao discloses that the external sheath and the internal sheath are connected to a proximal connector (92, Fig. 8).

17. As to claim **82**, Nakao discloses that the internal sheath comprises an imaging window (opening through which the optics 81 can be seen, Fig. 8) at its distal end.

18. As to claim **84**, Nakao discloses that the internal and external sheaths can be bended (Fig. 9 and Fig. 10 where it can be seen the external sheath being bent from expanded to collapsed, Col. 8, lines 11-15, wherein "rubber" is bendable).

19. As to claim **91**, Nakao discloses two longitudinal lines which define a plurality of separate channels between the sheaths (Fig. 7).

20. Claims **43** and **83** are rejected under 102(b) under another embodiment disclosed by Nakao et al.

21. As to claim **43**, Nakao discloses, in another embodiment, a sheath (Figs. 12A-12C) assembly for a probe, comprising: an internal sheath (122) configured to isolate a probe from body fluids; and an external sheath (Col. 9, lines 36-41) surrounding the internal sheath, the internal and external sheaths being connected to each other

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wherein at least the distal ends of the internal and external sheaths are flexible (because flexible is a relative term, everything has a certain amount of flexibility in it).

22. As to claim **83**, Nakao discloses that the internal and external sheaths can be folded (Fig. 12A).

23. Claims **43, 46, 80, 85, and 90** are rejected under 35 U.S.C. 102(b) as being unpatentable over Bacich et al. (U.S. Patent 5,749,889).

24. As to claim **43**, Bacich discloses a sheath (Fig. 3) usable for a probe comprising: an internal sheath (132) configured to isolate a probe from body fluids; and an external sheath (140) surrounding the internal sheath, the internal and external sheaths being connected to each other wherein at least the distal ends of the internal and external sheaths are flexible (because flexible is a relative term, everything has a certain amount of flexibility in it).

25. As to claim **46**, Bacich discloses that the internal and external sheaths are connected non-symmetrically radially (Figs. 3 & 4, where it can be seen that there the outer membrane is connected differently to the inner sheath at section 136).

26. As to claim **80**, Bacich discloses that the external sheath is formed with an internal notch capable of receiving a dovetail of a working tube (144).

27. As to claim **85**, Bacich discloses that the external sheath is non-elastic (Col. 14, lines 25-29).

28. As to claim **90**, Bacich discloses that the external sheath is non-self collapsible (Col. 14, lines 8-12).

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29. Claims **43, 48, 50, 78, 81, and 86** are rejected under 35 U.S.C. 102(b) as being unpatentable over Krasner et al. (U.S. Patent 4,676,228).

30. As to claim **43**, Krasner discloses a sheath (Fig. 3) usable for a probe comprising: an internal sheath (46) capable of isolating a probe from body fluids; and an external sheath (18) surrounding the internal sheath, the internal and external sheaths being connected to each other wherein at least the distal ends of the internal and external sheaths are flexible (because flexible is a relative term, everything has a certain amount of flexibility in it). Krasner's sheath is considered to be capable of isolating a probe because it is physically setting apart that section of the probe from body fluids.

31. As to claim **48**, Krasner discloses that the internal and external sheaths are connected substantially only at plurality of circumferential points at a distal end of the external sheath (Fig. 3, connected by 44a).

32. As to claim **50**, Krasner discloses that the internal sheath extends beyond the distal end of the external sheath (Fig. 3).

33. As to claim **78**, Krasner discloses that over most of the length of the sheath assembly, the external sheath is not attached to the internal sheath (Fig. 3).

34. As to claim **81**, Krasner discloses that the external sheath is sealed at its distal end (at 44a, Fig. 3).

35. As to claim **86**, Krasner's external sheath is stretchable (as it is made of urethane, Col. 6, lines 52-56).

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36. Claims **43** and **87** are rejected under 35 U.S.C. 102(b) as being unpatentable over Silverstein et al. (U.S. Patent 5,025,778).

37. As to claim **43**, Silverstein discloses a sheath assembly (Fig. 8) comprising an internal sheath configured to isolate a probe from body fluids (52), and an external sheath (54) surrounding the internal sheath, the internal and external sheaths being connected to each other, wherein at least the distal ends of the internal and external sheaths are flexible.

38. As to claim **87**, Silverstein discloses that the internal and external sheath have substantially the same thickness (Fig. 8).

39. Claims **43** and **48** are rejected under 35 U.S.C. 102(e) as being anticipated by Oneda et al. (U.S. Patent 6,461,294, herein referred to Oneda1).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

40. As to claim **43**, Oneda1 discloses a sheath assembly (Fig. 3) comprising an internal sheath configured to isolate a probe from body fluids (103), and an external sheath (300) surrounding the internal sheath, the internal and external sheaths being connected to each other, wherein at least the distal ends of the internal and external sheaths are flexible.

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41. As to claim **48**, Oneda1 discloses that the internal and external sheaths are connected substantially only at plurality of circumferential points at a distal end of the external sheath (connected at 340, Fig. 3).

Claim Rejections - 35 USC § 103

42. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

43. Claim **88** is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein (U.S. Patent 5,025,778) as applied to claim 43, further in view of Nakao et al. (U.S. Patent 5,217,001).

44. Silverstein discloses that the external member may be made of flexible materials such as rubber (Col. 5, lines 7-10) but does not disclose the material of the internal sheath. Nakao discloses an analogous device which uses rubber as the material for the internal sheath (Col. 8, lines 11-15). It therefore would have been obvious to one of ordinary skill in the art to modify Silverstein's inner sheath so that it is made of rubber and still predictably arrive at the same working invention. Furthermore, it has been held that it is within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

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45. Claim 89 is rejected under 35 U.S.C. 103(a) as being unpatentable over Silverstein (U.S. Patent 5,025,778) as applied to claim 43, further in view of Oneda et al. (U.S. patent 6,174,280, herein referred to as Oneda2).

46. Silverstein does not disclose that a rigid pipe section is located at the proximal end of the internal sheath.

47. Oneda2 discloses a sheath for a probe (Figs. 7-8) which serves to protect the probe while altering the bending characteristics of the probe with a rigid member (241) adhered to a proximal region of the sheath. This rigid member gives the ability of the operator to change the bending characteristics of the probe and therefore “allows one endoscope to be used effectively and efficiently for a range of procedures which typically require insertion tubes with different bending characteristics” (Col. 2, lines 50-54).

48. It therefore would have been obvious to one of ordinary skill in the art to modify Silverstein's internal sheath so that it had this rigid member in order to give it the advantages taught by Oneda, as noted above.

Conclusion

49. Any inquiry concerning this communication or earlier communications from the examiner should be directed to TINA NGUYEN whose telephone number is (571)270-1489. The examiner can normally be reached on M-Thurs 8:30-6:00.

50. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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51. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Linda C Dvorak/
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